

REMARKS/ARGUMENTS

The Advisory Action dated April 11, 2006 has been considered in view of the final Office Action dated January 26, 2006 (hereinafter Office Action) and Applicant's response thereto. Claims 1-35 remain pending in the application. Independent claims 1, 6, 14, 19, 24, and 30 have been amended. Reconsideration of the pending claims as amended and allowance of the application in view of the present response is respectfully requested.

The Examiner's comments presented in the Advisory Action have been carefully considered. Applicant appreciates the explanation provided by the Examiner regarding the pending claims and asserted prior art relative to same. Applicant has amended independent claims 1, 6, 14, 19, 24, and 30 to recite explicitly a feature believed to be implicit in Applicant's prior pending claims. Applicant's prior responsive arguments were, in part, directed to this feature and, as such, applicable portions of these arguments are reiterated hereinbelow.

Claims 1, 3, 6, 8, 11-14, 16, 19, 21, 24, 25, 27, 30, 31 and 33 stand rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,728,140 to *Salo et al.* (hereinafter "*Salo*") in view of U.S. Patent No. 5,545,210 to *Helland et al.* (hereinafter "*Helland*"). Claims 2, 4, 7, 9, 15, 17, 20, 22, 26, 28, 32 and 34 stand rejected under 35 U.S.C. §103(a) as being unpatentable over *Salo* in view of *Helland* and further in view of U.S. Patent No. 5,931,862 to *Carson*. (hereinafter "*Carson*"). Claims 5, 10, 18, 23, 29 and 35 stand rejected under 35 U.S.C. §103(a) as being unpatentable over *Salo* in view of *Helland* and further in view of *Stokes*.

Each of Applicant's independent claims 1, 6, 14, 19, 24, and 30 has been amended to recite, in some form, a pacing electrode having a fluoropolymer coating or sleeve provided on a majority of an exposed surface of the electrode or the active fixation arrangement of the electrode sufficient in coverage to inhibit exit block development yet facilitate electrical stimulation of cardiac tissue.

The exposed surface of the electrode or active fixation arrangement of the electrode in Applicant's claims, when read in light of Applicant's specification, refers to the tissue stimulating surface of the electrode, as was previously discussed in the prior responsive

communication. Applicant's amended claims now recite explicitly that a fluoropolymer coating or sleeve is provided on a majority of this exposed surface sufficient in coverage to inhibit exit block development yet facilitate electrical stimulation of cardiac tissue. In other words, and as previously argued, the fluoropolymer coating or sleeve provides for inhibiting exit block development and cardiac tissue stimulation.

Salo, at column 4, lines 27-30, teaches that:

As in the design depicted in FIG. 2, only one or so of the distalmost convolutions [of its helical or corkscrew tip] remains uninsulated while the remaining more proximal convolutions are coated with a suitable electrically insulating covering. [*alteration added*]

The coating provided on the exposed portion of *Salo*'s helical or corkscrew tip is an electrically insulating covering. *Salo* teaches that the insulation on its electrode is necessary so that the electrode provides no tissue stimulation to the right ventricular wall (due to the presence of the "insulation"), yet provides cardiac stimulating pulses to the left ventricle independent of the right ventricle (due to the presence of the bare electrode surface proximate the left ventricular septal wall). *See, e.g.*, column 1, lines 51-67 of *Salo*.

Thus, the only portion of the *Salo* electrode that defines a tissue stimulating surface is the bare distal convolutions. *Salo* teaches that these distal convolutions are bare (i.e., not covered), and are clearly not covered by a fluoropolymer coating or sleeve.

In contrast to the *Salo* electrode insulation arrangement, one skilled in the art would readily understand that Applicant's exposed electrode surface provided with a fluoropolymer coating or sleeve defines a tissue stimulating surface of the electrode. For example, tissue stimulation vis-à-vis Applicant's coated helical electrode is provided even where the entirety of the exposed helical electrode 420 is covered by polymer layer 425 according to Applicant's disclosure and claims.

Helland does not cure the deficiencies of *Salo*. As set forth in Applicant's prior responsive communications, *Helland* does not teach or suggest a coating or sleeve provided on a majority of the exposed surface of the fixation arrangement. *Helland* discloses a

bipolar active fixation lead having a helix 44 defining an inner electrode 46, an intermediate insulator 48, and an outer electrode 50, as shown in Figures 3-5 of *Helland*. The outer and central electrodes 50, 46 operate as a bipolar electrode pair. As can be seen in Figures 3-5 of *Helland*, the intermediate insulator 48 does not cover a majority of the exposed surface of the fixation member. The inner 46 and outer 50 electrodes form the majority of the exposed surface of *Helland's* fixation member and these elements are not covered by the insulator.

Salo expressly teaches that the tissue stimulating portion of its electrode is not covered by insulation (see above argument concerning independent stimulation of left and right ventricles). It is improper to combine references where the references teach away from their combination. *In re Grasselli*, 713 F.2d 731, 743, 218 USPQ 769, 779 (Fed. Cir. 1983). The references cited by the Examiner fail to suggest the desirability of the combination and provide no motivation to make the asserted combination as required to establish a *prima facie* case of obviousness. For at least these reasons, claims 1, 3, 6, 8, 11-14, 16, 19, 21, 24, 25, 27, 30, 31, and 33 are patentable over the combination of *Salo* and *Helland*.

Neither *Salo* nor *Helland* teaches or suggests all of the claims limitations of Applicant's amended claims. Because the references cited by the Examiner do not teach or suggest all of the claim limitations, Applicant's claims 1, 3, 6, 8, 11-14, 16, 19, 21, 24, 25, 27, 30, 31, and 33 are patentable over the combination of *Salo* and *Helland*.

Claims 2, 4, 7, 9, 15, 17, 20, 22, 26, 28, 32, and 34 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over *Salo* in view of *Helland* and in further view of Carson, US 5,931,862. Claims 5, 10, 18, 23, 29, and 35 are rejected under 35 U.S.C. § 103(a) as being unpatentable over *Salo*, in view of *Helland*, and in further view of Stokes, H356.

Each of the above-listed obviousness rejections relies on the teachings of *Salo* and *Helland*. Applicant asserts that the additional references, when combined with *Salo* and *Helland*, fail to render the claims listed above unpatentable. A *prima facie* case of obviousness requires that the asserted references teach or suggest all of the claim elements. In each of the combinations asserted above, none of the asserted references (*Salo*, *Helland*,

Carson, Stokes) teaches or suggests, for example, an electrode having a fluoropolymer coating or sleeve provided on a majority of an exposed surface of the electrode.

Neither *Salo* nor *Helland* describes this element for the reasons discussed above. *Carson* expressly teaches that portions of lead 12 not covered by the sheath include the distal pacing electrode 20, which is shown to include a helix or tine fixation element. See *Carson*, column 4, lines 34-36. *Stokes* describes a pacing lead that has a bore for passage of a drug to the stimulation and fixation site. The fixation element in *Stokes* does not have a coating or sleeve. Because, for each rejection made by the Examiner, the cited references do not teach or suggest all of the claim limitations of Applicant's invention, claims 2, 4, 5, 7, 9, 10, 15, 17, 18, 20, 22, 23, 26, 28, 29, 32 and 35 are patentable over the asserted combinations.

As discussed above, Applicant believes its amendments to the independent claims merely recite explicitly that which was implicit in the prior pending claims. Several decisions by the Federal Circuit have indicated that an amendment that only make express a recitation of a feature that was already inherent in the original claim is not a narrowing of the scope of the properly construed claim. *TurboCare v. General Electric Co.*, 264 F.3d 1111 (Fed. Cir. 2001); *Bose Corp. v. JBL, Inc.*, 274 F.3d 1354 (Fed. Cir. 2001) and *Interactive Pictures Corp. v. Infinite Pictures, Inc.*, 274 F.3d 1371 (Fed. Cir. 2001). Hence, Applicant respectfully submits that the amendments made to claims 1, 6, 14, 19, 24, and 30 have not narrowed the scope of these claims when properly construed.

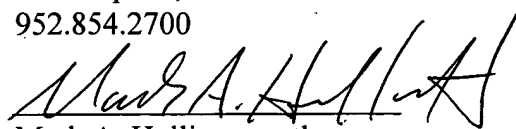
It is to be understood that Applicant does not acquiesce to Examiner's characterization of the asserted art or Applicant's claimed subject matter, nor of the Examiner's application of the asserted art or combinations thereof to Applicant's claimed subject matter. Applicant reserves the right to address in detail the Examiner's characterizations, conclusions, and rejections in future prosecution.

It is believed that the pending claims are in condition for allowance. Authorization is given to charge Deposit Account No. 50-3581 (GUID.076PA) any necessary fees for this filing. If the Examiner believes it necessary or helpful, the undersigned attorney of record invites the Examiner to contact him at to discuss any issues related to this case.

Respectfully submitted,
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Date: April 26, 2006

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